UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,677	04/15/2005	Margaret Forney Prescott	PA/4-32723A	1716

1095 7590 11/17/2009

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
FRAZIER, BARBARA S	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
11/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,677	PRESCOTT, MARGARET FORNEY	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1 and 9 are pending in this application. Claims 2-8 and 10-18 stand canceled.

2. Claims 1 and 9 are examined.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Day et al (US 2001/0036936).

The claimed invention is drawn to a method for the treatment of atherosclerosis in a patient in need of such treatment which comprises administering an effective amount of a bisphosphonate to the patient wherein the bisphosphonate is zoledronic acid or a pharmaceutically acceptable salt thereof or any hydrate thereof (see claim 1).

Day et al teach methods for promoting bone formation and/or preventing bone loss and/or treating atherosclerosis with a composition comprised of a polyphosphonate (abstract). Preferred polyphosphonates include 1-hydroxy-2-(1H-imidazol-1-yl)ethylidene-1,1-bisphosphonic acid (zolendronate, which Applicants have identified as

zoledronic acid) (see paragraphs 51 and 52 and claims 8 and 9). Day et al teach administration of effective amounts of the polyphosphonate (paragraphs 54-59).

Day et al do not specifically teach the use of zolendronate to treat atherosclerosis.

However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to treat atherosclerosis by administering an effective amount of zolendronate; thus arriving at the claimed invention. One skilled in the art would be motivated to do so, with a reasonable expectation of success, because Day et al fairly teach and suggest treatment of atherosclerosis comprising administration of a polyphosphonate, and also fairly teach and suggest zolendronate as one of the preferred polyphosphonates. Therefore, one skilled in the art would find it obvious to select zolendronate from the finite list of identified, predictable solutions of the choice of polyphosphonate, with the reasonable expectation of treating atherosclerosis.

Regarding claim 9, Day et al teach that the polyphosphonate may be administered locally (paragraph 19).

Response to Arguments

5. Applicant's arguments filed 10/27/09 have been fully considered but they are not persuasive.

In response to Applicant's argument that Day et al. does not disclose that polyphosphonate as single agents would be useful for the treatment of atherosclerosis, it is noted that Applicant's independent claim 1 contains the open-ended language "comprising", which is open-ended and does not exclude additional, unrecited elements

or method steps. See MPEP 2111.03. Therefore, the claims allow for the presence of other elements and method steps, such as the administration of a statin with the polyphosphonate, as taught by Day et al.

In response to Applicant's argument that the preferred polyphosphonate described in Day et al. is aledronate, and that the examples are specific to the use of aledronate, it is noted that Day et al fairly teach and suggest zolendronate as one of the preferred polyphosphonates (see paragraphs 51 and 52, and claims 8 and 9). Therefore, one skilled in the art would find it obvious to select zolendronate from the finite list of identified, predictable solutions of the choice of polyphosphonate, with the reasonable expectation of treating atherosclerosis.

Therefore, it is the Examiner's opinion that the claims are rendered obvious.

Conclusion

No claims are allowed at this time.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/Ashwin Mehta/
Primary Examiner, Technology Center 1600